REMARKS

Claims 1-14 are pending in the present application. Claims 1-5 have been amended herein.

Support for the amendments to claims 1-5 may be found throughout the specification, including the claims as originally filed. In particular, support for the amendments to claims 1-3 can be found on pages 11-12 and SEQ ID NO:2 and 4 of the instant application; pages 3-4, 12-16, 19, 22-23, and 32-34 of USSN 08/109,393 (the relevant portions of which are enclosed as Appendix A), to which the instant application claims priority and has incorporated its entirety by reference; and Example 7 of US Patent 6,130,316, to which the instant application claims priority and has incorporated its entirety by reference. No new matter has been added.

Amendment or cancellation of claims should not be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the right to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Species Election

On page 2 of the pending Office Action, the Examiner acknowledges Applicants' alleged election of the species "anti-inflammatory agents, and aspirin as the ultimate species in the Reply to Restriction Requirement, filed on 2/15/06." Applicants respectfully point out that a provisional election of the species "B7-2 encoding nucleic acids without additional molecules" and "sarcoma" was made, for search purposes only, in the Response to Restriction Requirement mailed on November 6, 2006. Accordingly, Applicants respectfully request that the correct election of species in the above-identified application be acknowledged.

Objections to the Specification

The Examiner has objected to page 1 of the specification for failure to update the status and relationships of the priority documents cited therein. Applicants have amended the specification herein to update said status and relationships. Applicants, therefore, respectfully request withdrawal of the objection.

Priority

Applicants respectfully point out that the filing date listed for the priority application, USSN 08/101,624, on page two of the Office Action is incorrect. The correct filing date is 7/26/1993. Upon request, Applicants can furnish a copy of the Filing Receipt confirming the foregoing date.

Trademarks

As requested by the Examiner, all spelling, Trademarks, and like errors in the specification will be corrected as they become known to Applicants.

Rejection of Claim 1 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner has rejected claim 1 as allegedly being indefinite in the recitation of "a B7-2 molecule" or "B7-2 molecules having the ability to costimulate a T cell and the ability to bind a CD28 or CTLA4." The Examiner contends that such terms only describe the molecules of interest by an arbitrary protein name.

Applicants respectfully traverse the rejection and assert that the instant claim particularly points out and distinctly claims the molecules of the invention. In an effort to expedite prosecution, however, Applicants have amended claim 1 to recite specific SEQ ID NOs associated with the claimed B7-2 molecules. With regard to the amendments to the claims, the Examiner is referred to pages 11-12 of the instant specification; pages 4 and 14-15 of USSN 08/109,393; and Example 7 of US Patent 6,130,316 for support for nucleic acid molecules encoding fragments of B7-2. The Examiner is further referred to pages 3 and 13 of USSN 08/109,393 and to SEQ ID NO:2 and 4 of the instant specification for support for the claimed percent homology. In particular, Applicants point out that SEQ ID NO:2 and 4 of the instant application are themselves 50% homologous with each other. Accordingly, Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-3 and 6-14 Under 35 U.S.C. § 112, First Paragraph - Written Description

Claims 1-3 and 6-14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that "[t]here is insufficient written description of the genus set forth in instant claim 1, which recites: 'a B7-2 molecule' or 'B7-2 molecules having the ability to costimulate a T cell and the ability to bind a CD28 or CTLA4.'"

Applicants respectfully traverse the rejection. However, as suggested by the Examiner and in the interest of expediting prosecution, Applicants have amended claims 1-3 to more clearly recite specific SEQ ID NOs associated with the claimed B7-2 molecules. With regard to the amendments to the claims, the Examiner is referred to pages 11-12 of the instant specification; pages 4 and 14-15 of USSN 08/109,393; and Example 7 of US Patent 6,130,316 for support for nucleic acid molecules encoding fragments of B7-2. The Examiner is also referred to pages 3 and 13 of USSN 08/109,393 and to SEQ ID NO:2 and 4 of the instant specification for support for the claimed percent homology. In particular, Applicants point out that SEQ ID NO:2 and 4 of the instant application are themselves 50% homologous with each other.

The amended claims presented herein satisfy the requirement under 35 U.S.C. § 112, first paragraph. In particular, the Examiner relies on the teachings of Riley et al., Coyle et al., Metzler et al., Attwood, and Skolnick et al. to argue that molecules having sequence similarity to costimulatory molecules, such as B7-2, can have different functions. Contrary to these teachings, Applicants submit that there is sufficient written description in Applicants' specification regarding the claimed B7-2 molecules to inform a skilled artisan that Applicants were in possession of the invention using nucleic acid molecules with defined functions at the time the application was filed, as required by section 112, first paragraph (see M.P.E.P. 2163.02). "Written description may be satisfied through disclosure of relevant identifying characteristics, *i.e.*, structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, First Paragraph Written Description Requirement.*

Applicants teach the chemical structures of SEQ ID NOs: 1-4. Based on the teachings in the specification and knowledge available at the time of filing, one of ordinary skill in the art would readily be able to envision the claimed nucleic acids encoding B7-2 molecules, or fragments thereof, that have the ability to costimulate a T cell and bind a CD28 or CTLA4 ligand. As such, Applicants provides ample guidance as to how one of skill in the art would test for whether the claimed B7-2 molecules were able to costimulate a T cell and bind a CD28 or CTLA4 ligand, including assays for determining antibody reactivity, cytokine production, and cellular proliferation (see pages 32 to 34 and Example 5 of USSN 08/109,393). Applicants further disclose how to generate the claimed fragments of B7-2 molecules and how to test for whether such fragments are able to costimulate a T cell and bind a CD28 or CTLA 4 ligand. Applicants also teach, for example, nucleic acid molecules encoding a B7-2 extracellular domain of SEQ ID NO: 2 or variable region-like domain of B7-2 of SEQ ID NO: 2, each fused to an immunoglobulin constant region (see, e.g., Example 7 of US Patent 6,130,316). Accordingly, based on the foregoing amendments and argument, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 1-3 and 6-14 Under 35 U.S.C. § 112, First Paragraph - Enablement

Claims 1-3 and 6-14 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner admits that the specification is enabling for certain nucleic acids encoding certain murine and human B7-2 molecules. The Examiner is of the opinion, however, that the specification does not reasonably provide enablement for "any 'B7-2 molecule' or 'B7-2 molecule having the ability to costimulate a T cell and the ability to bind a CD28 or CTLA4.'"

Applicants respectfully traverse the rejection. However, as suggested by the Examiner and in the interest of expediting prosecution, Applicants have amended claims 1-3 to more clearly recite specific SEQ ID NOs associated with the claimed B7-2 molecules. With regard to the claims amendments directed to nucleic acid molecules encoding fragments of B7-2, the Examiner is referred to pages 11-12 of the instant specification, pages 4 and 14-15 of USSN 08/109,393 (Appendix A); and Example 7 of US Patent 6,130,316. Support for the claim amendments pertaining to percent homology, the Examiner is referred to pages 3 and 13 of

USSN 08/109,393 and to SEQ ID NO:2 and 4 of the instant specification. In particular, Applicants point out that SEQ ID NO:2 and 4 of the instant application are themselves 50% homologous with each other.

With further regard to the amendments to the claims, we provide the following arguments for the record. As indicated above, Applicants teach the chemical structures of SEQ ID NOs: 1-4. Applicants also teach how to make the claimed fragments and homologues of these sequences (see, for example, page 16, the second paragraph of page 19, and the isolation of mRNA and construction of a cDNA library section at pages 22-23 of USSN 08/109,393). Moreover, the instant specification provides ample guidance as to how one of skill in the art would make and use the claimed invention by, for example, disclosing *ex vivo* modification of a tumor cell to express a costimulatory molecule (page 8), additional modification of a tumor cell to express MHC molecules (pages 12-17), and the types of tumor cells that may be modified (pages 17-18). Thus, one of ordinary skill in the art reading the foregoing teachings in Applicants' specification would have been able to make and use the claimed invention using only routine experimentation. In view of the foregoing amendments and argument, Applicants respectfully request reconsideration and withdrawal of the rejection.

Double Patenting Rejections

The Examiner has provisionally rejected claims 1-14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of issued U.S. Patent No. 6,723,705. Applicants respectfully request that the Examiner hold in abeyance all obviousness-type double patenting rejections based on said issued U.S. patent until allowable subjected matter is indicated, at which point Applicants will consider filing a terminal disclaimer.

CONCLUSION

Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1000. If any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to **Deposit Account No. 06-1448, Reference No. WYS-018.04.**

Respectfully submitted,
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